Applicant respectfully traverses all of these rejections. In view of the following remarks, reconsideration and withdrawal of all grounds of rejection are respectfully requested.

Applicant respectfully submits that both Hermann and Heck fail to meet the exacting standard for anticipation under 35 U.S.C. §102, with respect to independent claims 11, 24, and 35, as amended, or claims 12-23, 25-34, and 36-45, which depend either directly or indirectly therefrom, because neither Hermann nor Heck teaches (or suggests) each and every limitation of claims 11-45.

Applicant submits that each of Hermann and Heck fails to teach or suggest at least the valve recited in claims 11-45. Specifically, neither of these references teaches or suggests at least "foam material filling at least some of the length of the passageway in the elongated body portion" or "one or more self-sealing slits in the foam material," as is recited in amended independent claims 11, 24, and 35.

Hermann discloses an introducing catheter having a flexible sheath (16) and a hemostasis valve assembly (18) that is a housing (36) with a foam insert (38) disposed therein. See Hermann, col. 9, lines 58-60. Hermann does not teach or suggest, however, at least that the foam insert fills at least some of the length of the sheath.

Hermann also discloses that the foam insert (38) in its uncompressed configuration has an open axial lumen (52), more preferably being flared open at its proximal end (54). See Hermann, col. 10, lines 4-7 and FIG. 4. The lumen (52) closes when the insert (38) is confined within the housing (36). See Hermann, col. 10, lines 7-9 and FIG. 3. Hermann, however, does not teach or suggest at least that the foam insert has one or more self-sealing slits in it.

Heck discloses a partitioned hemostasis valve system (10) for use with a splittable sheath (20), with a partitioned hemostasis valve housing (12) that contains a partitioned hemostasis valve formed in at least two separate and distinct equal-sized valve sections (38, 40) made of pliant resilient rubber, such as silicon rubber, latex rubber, or foamed rubber of 20 to 60 durometer. Heck does not teach or suggest, however, at least that the partitioned hemostasis valve fills at least the some of the length of the sheath. In Heck, the valve system is distinct from the sheath.

Heck also does not teach or suggest at least that the pliant resilient rubber has one or more self-sealing slits. Heck instead discloses a valve formed of two separate portions. Thus, with respect to amended claim 11, Heck fails to teach or suggest at least that none of the slits extends in width to the inner surface of the sheath. Also, with respect to amended claim 24, Heck fails to teach or suggest at least that foam material is affixed to a portion of the inner surface of the sheath.

In addition, Applicant submits that each of Hermann and Heck fails to teach or suggest "the length of the foam material within the passageway being greater than the width of the foam material at any point within the passageway," as is recited in amended independent claims 11, 24, and 35. Applicant submits that neither Hermann nor Heck discloses the relation between the width and the length of their valves. With respect to the apparent reliance on the drawings of Hermann and Heck, Applicant submits that it is undisputed that, although the drawings are part of Hermann and Heck, supposed proportions of features in drawings are not evidence of actual proportions when the drawings are not to scale. When a reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. See M.P.E.P. §2125 (8th ed., August 2001). See also, Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc., 2000 U.S. App. LEXIS 18139; 55 U.S.P.Q. 2d (BNA) 1487 (Fed. Cir. 2000)(patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue).

Here, both Hermann and Heck are completely silent both as to whether the drawings are to scale and as to proportions or dimensions of the valves. In accordance with the M.P.E.P. and case law, therefore, it is improper to glean from either or both of these references that their valves meet the length and width recitations in amended independent claims 11, 24, and 35. Neither Hermann nor Heck teaches or suggests "the length of the foam material within the passageway being greater than the width of the foam material at any point within the passageway."

CONCLUSION

In view of the foregoing, Applicant respectfully requests reconsideration, withdrawal of all grounds of rejections, and allowance of claims 11-45 in due course. The Examiner is invited to contact Applicant's undersigned representative by telephone at the number listed below to discuss any outstanding issues.

Respectfully submitted,

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MARKED-UP VERSION OF THE AMENDED CLAIMS

11. (Amended) Apparatus for facilitating the insertion of a flexible medical device into a body, comprising:

(a) a sheath comprising

a proximal hub portion,

an elongated body portion extending distally from the proximal hub portion, at least some of the elongated body portion capable of being placed into the body, and

a passageway extending through the proximal hub and elongated body portions, the passageway being defined by an inner surface of the sheath; and

(b) a valve comprising

a foam material filling at least some of the length of the passageway <u>in the elongated body portion</u>, the length of the foam material within the passageway being greater than the width of the foam material at any point within the passageway, and

one or more self-sealing slits in the foam material, none of the slits extending in width to the inner surface of the sheath, the one or more slits capable of allowing the flexible medical device to pass therethrough and sealing around the device.

24. (Amended) Apparatus for facilitating the insertion of a flexible medical device into a body, comprising:

(a) a sheath, comprising

a proximal hub portion,

an elongated body portion extending distally from the proximal hub portion, at least some of the elongated body portion capable of being placed into the body, and

a passageway extending through the proximal hub and elongated body portions, the passageway being defined by an inner surface of the sheath; and

(b) a valve, comprising

a foam material filling at least some of the length of the passageway in the elongated body portion, the length of the foam material within the passageway being greater than the width of the foam material at any point within the passageway, the foam material being affixed to a portion of the inner surface of the sheath, and

one or more self-sealing slits in the foam material, the one or more slits capable of allowing the flexible medical device to pass therethrough and sealing around the device.

35. (Amended) Apparatus for facilitating the insertion of a flexible medical device into a body, comprising:

(a) a sheath, comprising

a proximal hub portion,

an elongated body portion extending distally from the proximal hub portion, and

a passageway extending through the proximal hub and elongated body portions; and

(b) a valve, comprising

an injected foam material filling at least some of the length of the passageway in the elongated body portion, the length of the foam material within the passageway being greater than the width of the foam material at any point within the passageway, and

one or more self-sealing slits in the foam material, the foam material and the one or more slits serving as [a] the valve in the passageway of the sheath.